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| 09/869,508      | 06/05/2002  | Bernd Dorken         | 101195-54           | 4142             |

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EXAMINER

NGUYEN, DAVE TRONG

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1632

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DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/869,508**

Applicant(s)

**Dorken**

Examiner

**Dave Nguyen**

Art Unit

**1632**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Apr 3, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10, 16, and 17 is/are pending in the application.
- 4a) Of the above, claim(s) 4 and 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-10, 16, and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Apr 3, 2003 is/are a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121:

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

Claims 11-12 have been added by the amendment filed April 2, 2003. Claims 4 and 5 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected claimed invention, there being no allowable generic or linking claim.

In view of the presence of canceled claims 11-15 in this as-filed application, claims 11-12 have been renumbered as claims 16-17.

This application has been assigned to a new examiner.

Claims 1-3, 6-10, 16, 17 are objected because the all claims under US standard must begin with article "A" (independent claim) or the article "The" (dependent claim). Correction is required.

The proposed drawings filed on April 3, 2003 have been considered and accepted by the examiner. However, correction of the formal drawings including those submitted on April 3, 2003 is required on the basis of the attached PTO-948.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly amended claims now embrace the claimed embodiments of the subject matter directed to a method of elevating the serum level of a transgene product comprising the use of any vector as claimed in claim 1 that is suitable for *in vivo* transgene expression. However, the claimed embodiment as indicated above does not contain any antecedent basis from the as-filed application, nor does the as-filed application provide any written support so as to enable a person skilled in the art to readily envision that application were in possession of the claimed invention of claim 17 at the time the invention was made. While the as-filed specification provides a working example utilizing an adenoviral vector comprising the YB-1 promoter operably linked to the human alpha 1-antitrypsin product in hepatocytes that proliferate on the third day after an administration of the adenoviral vector to the hepatocytes. However, such exemplification does not support s the claimed invention of claim 12, wherein any vector comprising two multi-cloning sites

flanking any transgene is employed in the invention. The summary of the invention as set forth on pages 4 and 5 of the as-filed specification does not appear to support for an invention that is contemplated for a method of measuring serum level of a transgene product by using the vector of claims 1 and 16, nor is it apparent from the as-filed specification as to what is exactly the intended utility of a method elevating the serum level of a transgene product as compared to unspecified conditions. Thus, the claimed invention of claim 17 is new matter and does not find written support from the as-filed specification. As such, a skilled artisan would not have recognized that applicant was in possession of the claimed invention of claim 12.

Claims 1-3, 6-10, 16, 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is based on the same reasons as set forth in the previous office action, pages 6-8.

Applicant's response (page 6 of the response) has been considered by the examiner but is not found persuasive for the reasons of record.

More specifically, applicant asserts that by providing just the description of only one particular species of YB-1 promoter consisting nucleotides 453-2150, applicant meets the written description requirement. However, it is not sufficient to support the present claimed invention directed to numerous number of species of mutants and/or variants of the YB-1 promoter consisting essentially of nucleotides 453-2150 in the YB-1 promoter sequence, gene bank Acc. # X96666, page 6 of the as-filed specification) as claimed in the pending claims, with no specific common chemical structure so as to exhibit applicant's intended utility of a tissue specific promoter, because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any and/or all other material(s) of nucleotide sequence(s) of YB-1 like promoter having any of the biological functions as contemplated by the specification and the claims. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which is not conventional in the art as of applicants effective filing date. Claiming unspecified molecular structures of nucleotide sequences and/or products that must possess the biological properties as contemplated by applicant's disclosure

without defining what means will do so is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). The skilled artisan cannot envision the detailed structure of a genus of the claimed FGF-like transgenes that must exhibit any of the contemplated biological functions, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures and/or methods disclosed in the as-filed specification. Thus, in view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed.

Applicant appears to indicate that the rejection states that the relationship among promoter, transgene and MCS are not taught in the as-filed specification. However, the issues as stated in the office action are that the skilled artisan would not have been able to envision the detailed chemical structure of a representative number of species of mutants and deletion variants on the basis of one specific YB-1 promoter consisting essentially of nucleotides 453-2150 in the YB-1 promoter sequence, gene bank Acc. # X96666. Furthermore, the skilled artisan would not, at the time the invention was made, have been able to recognize the chemical structure of a representative number of species of regulatory elements that must either exhibit the ability to regulate (activating or suppressing activity) the activity of the exemplified YB-1 promoter, let alone any other mutant of YB-1 promoter. Thus, applicant's assertion is not found persuasive.

Should applicant amend the claims so as to limit applicant's claimed invention to the exemplified YB-1 promoter, and/or other limitations that find written support from the as-filed specification, the amendment would obviate the rejection of the vector claims.

*Sequence Rules and objection to the specification*

The as-filed application recites the specific disclosed promoter which consists essentially of nucleotides 453-2150 in the YB-1 promoter sequence, gene bank Acc. # X96666, which is clearly embraced by the claimed invention. Applicant is required to comply with the requirements of 37 CFR 1.821 through 1.825. Note a SEQ ID NO: disclosing the sequence as intended by applicant at the time the invention was made is required and that neither the paper copy of the sequence listing the intended nucleotides 453-2150 nor the computer readable can introduce new matters. Note also that the sequence rules apply to all sequences in a given application, whether claimed or not. All such sequences are relevant for the purposes of building a comprehensive database and properly assessing prior art. It is therefore essential that all sequences, whether only disclosed or also claimed, be included in the database.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of


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such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen  
Primary Examiner  
Art Unit: 1632

  
DAVE T. NGUYEN  
PRIMARY EXAMINER